Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C.

November 28, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 2005D-0385 – FDA "Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information"

Dear Sir/Madam:

On behalf of the Johnson & Johnson family of companies, I am providing the following comments and recommendations in response to the FDA *"Draft Guidance for Industry on Using Electronic Means to Distribute Certain Product Information,"* released for comment in the Federal Register (70 FR 19731, September 30, 2005). Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical, and medical devices and diagnostics markets. The more than 200 Johnson & Johnson operating companies employ approximately 114,000 men and women in 57 countries and sell products throughout the world.

Johnson & Johnson commends FDA's determination that electronic communications can satisfy the regulatory requirements for disseminating certain recall and other safety information under 21 CFR §§ 7.49 and 200.5. We agree that use of electronic means to communicate important safety information is appropriate in that it allows manufacturers to provide the information as rapidly as possible to the appropriate audience(s). Some Johnson & Johnson companies have been using electronic means to disseminate important product information for several years, for example one company has been posting recall information to its website since 2000 and sending limited direct e-mail notifications since 2004.

Overall, the discussion in the draft guidance regarding using electronic means to distribute certain product information is clear and appears to cover communications relevant to a product recall and Dear Healthcare Professional Letter (Dear HCP Letter). Below we present our specific comments on the draft guidance, including suggestions to modify the text.

Specific Comments:

- FDA states that the guidance applies "to those instances, not addressed in any regulation, where we recommend that manufacturers and distributors voluntarily convey certain safety information about their products to members of the public. We encourage the use of electronic communications for conveying all such important product safety information." Further clarification is needed as to what types of safety information not covered by regulation is intended to be covered by this guidance.

- The discussions in the draft guidance emphasize e-mail dissemination rather than website delivery or CD delivery of material. On a case-by-case basis, we anticipate using a combination of electronic means to properly alert the public of product safety information. We suggest the guidance be revised to specifically extend electronic communication to include email, website and CD dissemination.

- In Section II of the draft guidance, FDA states, "Verification of receipt or delivery is less expensive and can be automatically accomplished. Any necessary follow-up (such as when receipt of the e-mail is not acknowledged) also can be accomplished electronically. If receipt is never acknowledged, the sender can resort to more traditional methods of notification." In addition, the Agency states in Section IV of the guidance, "In evaluating the effectiveness of the recall, the recall check should indicate that the recall notification was received, read, understood, and/or instructions followed, and reach the appropriate level in the distribution chain."

    - It appears that the procedures described in Section II of this draft guidance are more burdensome than current requirements for Dear HCP Letters. We are required to produce proof of mailing Dear HCP Letters, but the regulations do not require us to secure verification of receipt. Furthermore, we are not required to send additional communications if we are not able to verify that our initial Dear HCP Letter has been received. The draft guidance implies that proof of receipt should be obtained and, if it is not, manufacturers should "resort to more traditional means of notification." Verification requirements for electronic communication should not be more burdensome than for communication by ordinary mail.

    - The referenced statements in the draft guidance imply that it is easy to determine, through monitoring of e-mails, whether recall notification and instructions are read, understood, and followed. However, this is not the case. Similar to letters, once the communication has been delivered, there are limited ways of tracking "read, understood and/or instructions followed." Although more stringent that current requirements, automatic tracking of delivery/read receipts may provide assurance regarding the effectiveness of the electronic communication.

- Section III includes the following text of regulatory provisions in 21 CFR § 7.49(c)(1), "a recall communication should... (v) [p]rovide a ready means for the recipient to report...whether it has any of the product, e.g. by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm." Please clarify whether allowing the recipient to electronically reply to the email notification with the requested information would satisfy this requirement.

- In the last paragraph of Section III, the Agency notes that to the extent possible, email and other electronic communications should follow the formatting and heading specifications described in 21 CFR §§ 7.49(b) and 200.5. We believe the use of consistent, concise and specific subject lines and headers should be implemented because uniform subject lines and structure are very important for the recipient to identify the type of communication being received and therefore apply the appropriate level of attention to the email. We believe this formatting should be consistent for all manufacturers. Therefore, we suggest FDA define the formatting parameters for subject lines and headers in email dissemination of recall information and Dear HCP Letters.

- In Section IV of the draft guidance, FDA briefly discusses the applicability of Part 11 requirements to electronic dissemination of product information. We interpret FDA's discussion and Part 11 guidance (*Guidance for Industry: Part 11, Electronic Records: Electronic Signatures – Scope and Application*) to mean that electronic communications subject to 21 CFR §§ 7.49(b) and 200.5 are also subject to Part 11. For clarity, the guidance should specifically state whether this is the case.

In closing, we would like to thank the Agency in advance for its thoughtful consideration of our comments and recommendations.

Sincerely,

Bonnie Goldmann

Bonnie J. Goldmann, MD
Sr. Vice President
Global Regulatory Affairs & Quality Assurance
Johnson & Johnson Pharmaceutical Research & Development